

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/EP2004/006323

International filing date (day/month/year)
11.06.2004

Priority date (day/month/year)
25.06.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/46

Applicant
BIDOIA S.A.S. DI GIANFRANCO BIDOIA E C.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 eprmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Storer, J

Telephone No. +49 89 2399-7247



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006323

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 in written format
 in computer readable form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006323

Box No. II Priority

1. The following document has not been furnished:

- copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|-----------------------|
| Novelty (N) | Yes: Claims | 3-7,10-16,20-24,27,28 |
| | No: Claims | 1,2,8,9,17-19,25,26 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 3-7,10-16,20-24,27,28 |
| Industrial applicability (IA) | Yes: Claims | 1-28 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
D1: US-A-5 842 786 (SOLOMON ALAN) 1 December 1998
D2: US-A-4 277 184 (SOLOMON ALAN) 7 July 1981
D3: US 2002/092871 A1 (BURCHETT RONNIE ET AL) 18 July 2002
2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 2, 8, 9, 17-19, 25 and 26 is not new in the sense of Article 33(2) PCT.
 - 2.1 The document **D1** discloses (the references in parentheses applying to this document): a mixing and distribution device (10) for fixing paste, particularly for multicomponent bone cement, comprising a box-like body (12) that forms internally a receptacle (14) that is closed in an upper region by a detachable and substantially fluid-tight lid (34), inside which means (29) for mixing the components of the fixing paste are accommodated, said mixing means (29) being coupled to a piston (36) that forms, inside said receptacle (14), a venting chamber toward said lid and a mixing chamber toward the bottom of said receptacle (14), said mixing chamber being connected to a channel (21) for distributing bone cement, which is controlled by valve means (22), said venting chamber being instead connected to a venting channel (72), which can be functionally associated with suction means, wherein said mixing means (29) are constituted by longitudinally elongated mixing blades (46) that are arranged to slide within complementary through slots (68) formed in said piston (36), a rotation pivot (60) being further locked coaxially on said piston (36) and being arranged so that it can slide through a corresponding fluid-tight hole (63) formed in said lid (34), said rotation pivot (60) being associative with corresponding rotation means (59) that can be operated by a user during mixing of the multicomponent paste, said device (10) further comprising a handgrip (84) for a single hand of the user, with which means (88) for the translational motion of said rotation pivot (60) together with said piston (36) toward the bottom of said receptacle (14) are associated, said means (88) being actuatable with the same hand associated with said handgrip

(84), said venting and mixing chambers being mutually connected for the passage of gaseous fluids (see column 2, line 57 to column 3, line 10, column 3, line 23 to column 6, line 50 and the figures).

- 2.2 Thus, document D1 discloses all of the technical features of claim 1. Furthermore, the disclosure of document D1 anticipates the subject-matter of dependent claims 2, 8, 9, 17-19 and 26 (see column 2, line 57 to column 3, line 10, column 3, line 23 to column 6, line 50 and the figures).
- 2.3 The same result with respect to the lack of novelty of the subject-matter of claim 1 is obtained with document D2 (see column 2, line 61 to column 3, line 18, column 3, line 31 to column 4, line 4, column 4, line 30 to column 6, line 66 and the figures). In addition, document D2 discloses the subject-matter of claim 25 (see column 2, line 61 to column 3, line 18).
- 2.4 Therefore, the subject-matter of claims 1, 2, 8, 9, 17-19, 25 and 26 is not novel and as such does not meet the criteria of Article 33(2) PCT.
3. The features of dependent claims 3, 27 and 28 have already been employed for the same purpose in a similar device, as disclosed in document D3 (see paragraph 31 to paragraph 38, paragraph 44 to paragraph 46 and figures 1-5). It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claims 3, 27 and 28. Therefore, the subject-matter of claims 3, 27 and 28 lacks an inventive step, contrary to Article 33(3) PCT.
4. Claims 4-7, 10-16 and 20-24 concern slight constructional changes in the device of claim 1 which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claims 4-7, 10-16 and 20-24 also appears to lack an inventive step, contrary to Article 33(3) PCT.
5. Claim 1 has not been correctly delimited with respect to the closest prior art (i.e. either document D1 or D2), which would have been appropriate (Rule 6.3(b) PCT).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.
PCT/EP04/06323

6. The documents D1, D2 and D3 should have been mentioned in the description and the relevant background art therein briefly discussed (Rule 5.1(a)(ii) PCT).